

## **REMARKS**

### **Amendments**

Claims 5-12 and 17-30 are canceled. Claims 34 and 41 have been amended. Claims 38-40 have been canceled. The amendments to the claims do not constitute new matter and are completely supported throughout the specification and originally filed claims. More particularly, the amendments to claims 34 and 41, drawn to a transgenic mouse whose genome comprises a disruption in the endogenous mouse anaphylatoxin C3a receptor gene, and a method of producing said mouse can be found, for example, at page 10, line 1 through page 16, line 22, and at page 53, line 1 through page 55, line 13, of the specification.

The foregoing amendments are made solely to expedite prosecution of the application and are not intended to limit the scope of the invention. Further, the amendments to the claims are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. The Applicants reserve the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

Upon entry of the amendment, claims 34-37 and 41-42 are pending in the instant application.

### **Rejections**

#### ***Rejection under 35 U.S.C. § 101***

The Examiner has rejected claims 34-42 under 35 U.S.C. § 101 as allegedly not supported by either a credible asserted utility or a well established utility. Applicants respectfully traverse the rejection.

The Examiner specifically alleges that the specification allegedly fails to discuss that a phenotype of reduced thymus weight, reduced thymus size, or reduced thymus to body weight ratio, which is exhibited by the claimed mouse, correlates with any disease or disorder. Therefore the Examiner concludes that the utility asserted by the specification, specifically for screening agents that may affect a phenotype, does not appear credible. Applicants respectfully disagree with these conclusions.

Claims 34-37 and 41-42 recite a transgenic mouse whose genome comprises a homozygous disruption in the anaphylatoxin C3a receptor gene which exhibits, relative to a wild-type mouse, increased susceptibility to seizure, a stimulus processing disorder, reduced

thymus weight, reduced thymus size or reduced thymus to body weight ratio. Claims 38-40 have been canceled.

The Applicants submit that the specification as originally filed provides ample guidance related to the utility of the transgenic mice as claimed. For example, as acknowledged by the Examiner, the specification discloses that the transgenic mice may be used to determine the effect of agents on a phenotype exhibited by the transgenic mice, such as, for example, seizure susceptibility, stimulus processing, or thymus weight or thymus size (see, for example, Page 20 of the instant specification). It is well established in the art that a transgenic mouse would be useful for such screening procedures. With regard to a phenotype such as abnormal or reduced thymus weight or size, the claimed mice would be known by the skilled artisan as useful for testing whether agents are capable of affecting phenotypic characteristics of the thymus, and in particular the weight or size of the thymus. As another example, the transgenic mice have been disclosed to be useful for the determination of the effect of agents on the expression or function of the disrupted anaphylatoxin C3a gene, and, more particularly, can be used to test agents that recover the disrupted expression or function of the gene (see, for example, Pages 20-21 of the specification). The skilled artisan would know that agents that affect expression or function of the anaphylatoxin C3a receptor would be assumed to have an effect on the thymus phenotype, and specifically on the reduced thymus size or weight, as described in the specification and recited in the pending claims.

As the transgenic mice as claimed have been demonstrated to have a well-established utility, which would be recognized by one of skill in the art, Applicants request withdrawal of the rejection under 35 U.S.C. § 101 for lack of utility.

***Rejection under 35 U.S.C. § 112, first paragraph***

***Utility:*** The Examiner has rejected claims 34-42 under 35 U.S.C. § 112, first paragraph, for lack of utility for the reasons set forth in the above rejection under 35 U.S.C. § 101. As Applicants have overcome the rejection for lack of utility for the reasons set forth above, it is appropriate to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

***Enablement:*** The Examiner has rejected claims 34-42 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants respectfully traverse the rejection, but

submit that the rejections have been overcome in light of the amendments to the claims and remarks below.

In one aspect, the Examiner has rejected the claims based on the lack of enablement for disrupting any anaphylatoxin C3a receptor gene other than that set forth by SEQ ID NO:1. Applicants have overcome this aspect of the rejection by including the word “the” prior to the phrase “endogenous mouse anaphylatoxin C3a receptor gene” as suggested by the Examiner.

In another aspect of the rejection, the Examiner asserts that claims 38-42 encompass chimeric animals. Applicants have overcome this aspect of the rejection by amending the claims to recite a transgenic mouse “whose genome comprises” a disruption in the anaphylatoxin C3a receptor gene.

Finally, the Examiner asserts that claims 38-42 encompass transgenic mice comprising a heterozygous disruption in the endogenous mouse anaphylatoxin C3a receptor gene. As the Examiner alleges the specification does not teach a phenotype for such mice, one of skill in the art would not know how to use this mouse. The Applicants respectfully disagree. However, the pending claims now relate to a transgenic mouse whose genome comprises a homozygous disruption and a method of producing such a mouse, wherein the mouse exhibits a phenotype enabled by the specification. Therefore, this aspect of the rejection is no longer relevant.

The Applicants respectfully traverse each of the above aspects of the rejection. However, in light of the amendments to the claims and remarks above, the rejection under 35 U.S.C. § 112, first paragraph no longer relevant.

**Written Description:** The Examiner has rejected claims 34-42 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the claims allegedly encompass more than one anaphylatoxin C3a receptor gene, whereas the specification describes one mouse anaphylatoxin C3a receptor gene. Applicants respectfully traverse the rejection.

Applicants submit that, as described in the specification, for example, at pages 2-3 and pages 7-8, one anaphylatoxin C3a receptor gene exists in a mouse. Applicants have described the anaphylatoxin C3a receptor gene (human and mouse) and demonstrated in sufficient detail disruption of this anaphylatoxin C3a receptor in a mouse, including the phenotypic effects

observed as a result of the disruption. Further, Applicants have included the term “the” preceding the phrase “endogenous mouse anaphylatoxin C3a receptor gene” as suggested by the Examiner to overcome the enablement rejection above. The skilled artisan would recognize, in light of Applicants’ disclosure, that Applicants were in possession of the invention as presently claimed. Therefore, Applicants believe that the present invention, specifically a transgenic mouse whose genome comprises a disruption in the endogenous mouse anaphylatoxin C3a receptor gene, is adequately described in the specification in order to fulfill the written description requirements set forth in 35 U.S.C. § 112.

It is believed that the claims are currently in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-171.

Respectfully submitted,

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Kelly L. Quast  
Kelly L. Quast, Reg. No. 52,141

Deltagen, Inc.  
1031 Bing St.  
San Carlos, CA 94070  
(650) 569-5100